Remarks

Applicant responds to the Final Rejection of the Official Action of June 21, 2010 with this Request for Continuing Examination pursuant to the provisions of 35 USC 132 and 37 CFR 1.114. This response, reply and amendment is a submission in full compliance with 37 CFR 1.114(c). It contains amended claims and fully responds to the objections and rejections of the Examiner in her Final Rejection. Accordingly, and as provided by 37 CFR 1.114(d), Applicant requests that the Patent Office withdraw the finality of the Official Action of June 21, reopen prosecution of the application and continue the examination of his application for a patent.

In responding to the Final Rejection, Applicant wishes to first draw the attention of the Examiner to the IDS which is submitted herewith and more specifically to page 61 of the cited PCT Application WO 99/62403 which was published on December 9, 1999, more than one year prior to the effective date of the present application of October 3, 2002. This EPO application was filed by the present inventor and contains much of the same disclosure as Application, 09/324,759 (now U.S. Patent No. 6,807,965) which was incorporated by reference into this application at Paragraph No. 0006. At page 61 of the PCT application and at Column 24 of the prior US Patent, is a disclosure of a generic concept of using "orthogonal redundancy" in the sedation system "to insure maximum safety and effectiveness" in connection with Dr. Hickle's sedation system.

In considering the patentability of the present claims, Applicant request serious scrutiny of his invention as presently claimed and a careful consideration of the mandates of the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966); *KSR Int'l Co. v.Teleflex Inc.*, 550 U.S 398 (2007), and the 2010 KSR Guidelines Update of the USPTO as published in the Federal Register on September 1, 2010.

Applicant's inventions are directed to sedation and pain relief rather that "general anesthesia" which is the state of "unconsciousness." Indeed numerous painful and unpleasant procedures such as colonoscopies, pacemaker placement, radiological procedures, wound dressings, etc do not require "general anesthesia" and the patient's pain and anxiety for such procedures can be adequately controlled by sedation without a placing the patient under general anesthesia—and without the presence of an anesthesiologist.

However, there are numerous problems in sedation induced without the presence of an anesthesiologist—problems that extend from ventilation suppression, to airway blockage, to cardiovascular problems. Applicant's invention is the first known computed assisted device to assist a non-anesthestist clinician to safely sedate a patient during a medical procedure – and avoid such problems. Indeed, Applicant is the first to invent a concept of eliminating the high cost of the operating room and its associated ventilation equipment as well as the high cost of an anesthesiologist during many medical procedures. As stated in the application, Serial No. 09/324,759, incorporated by reference into this application at column 6, lines 57+:

> The invention is directed to apparatuses and methods for alleviating a patient's pain and anxiety before and/or during a medical or surgical procedure and for alleviating a patient's post operative or other post-procedural pain or discomfort while simultaneously enabling a physician to safely control or manage such pain and/or anxiety. The costs and time loss often associated with traditional operating room settings or other requirements or desires for the presence of anesthetist may thus be avoided.

Moreover, the present inventions are directed to enhancing the inventions of the original application by adding a further specific, safety concepts of orthogonal redundant monitoring to the system and by integrating same into the control of the infusion of the sedative drug in a safe and effective manner.

In considering patentability of Applicant's inventions, *Graham v. John Deere*, *supra*, mandates that the Patent Office consider the differences between Applicant's claimed invention and the prior art.

In rejecting Applicant's claimed inventions, the Examiner has relied upon the Burton reference. That reference has nothing to do with sedation and/or pain relief by a non-anesthetist during a medical procedure. Indeed, Burton's discloses the opposite: they are related to assisting the anesthesiologist evaluate the depth of anesthesia of a patient during a surgery—and to achieve adequate anesthesia while avoiding the use of excessive drugs. See Par 0019, page 2 of Burton and paragraph 0021 of Burton.

The Examiner also relies upon the Feldman reference with fuses independent measures of physiological measurement to provide a physician with a quantitative indication of the patient's condition. Feldman says nothing of either "general anesthesia" as discussed by Burton or of sedation without general anesthesia as disclosed by Applicant. Moreover, there is no evidence record that would bring these two references together to accomplish any aspect of the claimed sedation by a non-anesthetist without general anesthesia.

Indeed, the combining of these two references under 35 USC § 103 is devoid of the required, articulated reasoning mandated by the Supreme Court in *KSR Int'l Co. v.Teleflex Inc.*, 550 U.S 398 (2007). In that case, the Court reemphasized that the rejections, as made in this case, cannot be sustained on a "mere conclusory statement." At page 418, the Court wrote:

> To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (.[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. (Emphasis added).

Indeed, one can study the Burton and the Feldman reference forever and a day, and never discern a valid reason or evidentiary support for bringing these two references together. Moreover, even if brought together, they would only result in a combination of physiological factors and general anesthesia—and completely fail to assist the skill of the art to achieve any concept of safe sedation without the presence of an anesthesiologist and the high cost of an operating room. Clearly, the unarticulated conclusion that these references can be combined results solely from the use of improper hindsight using Applicant's invention as a roadmap. Such is respectfully submitted to be clear error! As stated by the U.S. Supreme Court in the *KSR* decision at page 421:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U. S. at 36 (warning against a .temptation to read into the prior art the teachings of the invention in issue. and instructing courts to guard against slipping into the use of hindsight. . (quoting *Monroe Auto Equipment Co.* v. *Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964). *KSR Int'l Co. v.Teleflex Inc.*, 550 U.S 398, 421 (2007).

As further stated by the Federal Circuit Court of Appeals:

> When prior art references require selective combination by the court to render obvious a subsequent invention there must be some reason for the combination other than the hindsight gleaned from the invention itself. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n.4, 221 USPQ 929, 933 & n. 14, (Fed. Cir. 1984). There must be `something in the prior art to suggest the desirability, and thus the obviousness, of making the combination'. *Lindemann Maschinenfabric GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir.. 1984). *Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985).*

In sum and substance, there is no evidentiary basis or valid reasoning in this record that permits the combination of the diverse Burton and Feldman references to meet the claims of Applicant's inventions.

Accordingly, the prior rejections of the Examiner should be withdrawn.

Moreover, Applicant's prior PCT application with the generic disclosure of orthogonal redundancy is no bar to the more specific claims presented here. That application is directed to a generic concept of orthogonal redundant monitoring and does to place the present, specific claims in the possession of the person of ordinary skill in the art. These specific improvements are the subject of the presently claimed non-obvious inventions.

Conclusion

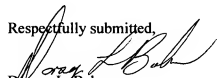
In sum, Applicant respectfully submit that the rejection of his application is in error for a plurality of reasons.

1. The rejection is premised upon mere conclusory statements—devoid of the required articulated reasoning with rational underpinning. *KSR Int'l Co. v.Teleflex Inc.*, 550 U.S 398, 418 (2007);

2. The rejection is improperly based upon hindsight and uses Applicant's application to arbitrarily pick and choose various elements from the prior art patents in further violation of the mandate of *KSR Int'l Co. v.Teleflex Inc.*, 550 U.S 398, 421 (2007).

Accordingly, the rejections should be withdrawn and a notice of allowance and the grant of a patent should be forthcoming.

Respectfully submitted,



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